K123220

MAR 0 1 2013

510(k) Summary

Submitter Name: Submitter Address:	Vertex Dental B.V. Johan van Oldenbarneveltlaan 62 3705HJ Zeist The Netherlands
Phone Number: Fax Number:	0031 306 976 780 0031 306 955 188
Contact Person:	Mason Diamond, DDS
Date Prepared:	January 17, 2013
Device Trade Name:	Vertex™ ThermoSens Rigid
Common Name	Denture base material
Classification Name, Number & Product Code:	resin, denture, relining, repairing, rebasing 872.3760 EBI
Predicate Devices:	TCS® Unbreakable - K053060 (Thermoplastic Comfort Systems, Inc.) Lucitone® FRS™ Flexible Dental Resin - K992956 (Densply International)
Device Description and Statement of Indications For Use	Device Description: Vertex™ ThermoSens Rigid is a thermoplastic material that is intended to be used in the fabrication of removable full and partial dental prostheses. The product is based on a compounded mixture of Polyamide and pigments. The Vertex™ ThermoSens material is incorporated in an aluminium tube, which is heated up to 280 degrees Celsius. After a heating period of 18 minutes, the material is injected into the flask by pressure. The technique can be done in an automatic injection machine or manually. The preparations of the model and flask are according to standard procedures of the dental technique. An instruction for use is in writing, film and pictures available. Also a course can be taken to learn the technique and work with the product.

Indications For Use:

Vertex™ ThermoSens is a thermoplastic material that is intended to be used in the fabrication of removable full and partial dental prostheses. The product is based on a compounded mixture of Polyamide and pigments

Summary of Technological Characteristics

All of the components found in the Vertex™ ThermoSens Rigid denture base material have been used in legally marketed devices and were found acceptable for dental use.

Substantial Equivalence

The Vertex™ ThermoSens Rigid denture base material is substantially equivalent to TCS Unbreakable (K053060) with respect to Indication for Use, Intended Use and Physical Properties (according to ISO 20795-1:2008 standard); and substantially equivalent to Lucitone® FRS™ Flexible Dental Resin - K992956 with respect to Composition. As a result of this analysis, the Vertex™ ThermoSens Rigid poses the same types of questions about safety or effectiveness as the existing predicate device.

Indications for Use/Intended Use
As presented in the table below, even though there is variation in the wording between the Vertex™ ThermoSens Rigid compared to the predicated devices, TCS Unbreakable (K53060) and Lucitone® FRS™ Flexible Dental Resin (K992956), the proposed device has the same Intended Use and similar Indications for Use statement. As a result of Indication for Use and Intended Use, the Vertex™ ThermoSens Rigid is Substantially Equivalent to that of the predicate devices.

Composition of Polymer
As presented in the table below, the Polyamide 12 polymer in the Vertex™ ThermoSens Rigid is the same as that in the Lucitone® FRS™ Flexible Dental Resin (K992956). As a result of Composition of Polymer, the Vertex™ ThermoSens Rigid is Substantially Equivalent to that of the predicate device.

Physical Properties (ISO 20795-1:2008 Testing)
As presented in the table below, the physical properties of the Vertex™ ThermoSens Rigid are equivalent to that of the TCS Unbreakable (K53060) predicate device, as determined by conformance to the ISO 20795-1:2008 testing requirements for dental materials. It is important to note that the Vertex™ ThermoSens Rigid was tested against TCS Unbreakable predicate by the Sponsor, and while the Lucitone® FRS™ Flexible Dental Resin (K992956) was not included in this tesing. As a result of the Physical Properties evaluation, the Vertex™ ThermoSens Rigid is Substantially Equivalent to that of the predicate devices.

Conclusion

The information discussed above demonstrates that the Vertex™ ThermoSens Rigid denture base material is substantially equivalent to the predicate devices.

Summary of Technical Characteristics

Feature	Vertex™ ThermoSens Rigid	TCS Unbreakable	Lucitone® FRS™ Flexible Dental Resin
510(k) Number	Not yet assigned	K053060	K992956
Manufacturer	Vertex Dental B.V.	Thermoplastic Comfort Systems, Inc.	Densply International
Classification # & Product Code	872.3760 EBI	872.3760 EBI	872.3760 EBI
Indications for Use	Vertex™ ThermoSens is a thermoplastic material that is intended to be used in the fabrication of removable full and partial dental prostheses. The product is based on a compounded mixture of Polyamide and pigments.	TCS® Unbreakable is a break resistant material used in the fabrication and repair of base plates for removeable dental prosthetic appliances where superior flexibility and patient comfort for the lifetime of the prosthetic are significant concerns. This includes, but not to be limited to, full and partial dentures, orthodontic devices, occlusal splints, and night guards.	Used for fabrication of partial or full removable dentures, as well as occlusal splints and nightguards.
Intended Use	Fabrication of removable dental prosthetic devices, such as full and partial dentures.	Fabrication and repair of removable dental prosthetic devices, such as full and partial dentures, orthodontic devices, occlusal splints, and night guards.	Fabrication of partial or full removable dentures, as well as occlusal splints and nightguards.
Composition of Polymer	Polyamide 12	Polyamide 12	Polyamide 12
Physical Properties (ISO 20795-1:2008 requirement)			Not Tested by Sponsor.
Impact Strength (≥ 7.0 kJ/m²)	8.0 ± 7.0 kJ/m²	8.5 ± 1.2 kJ/m²	
Flexural modulus (≥ 1000 MPa)	1339 ± 54 MPa	353 ± 4.24 MPa	
Water absorption (≤ 32.0 µg/mm³):	31.2 ± 0.8 µg/mm³	14.6 ± 0.4 µg/mm³	
Water solubility (≤1.6 µg/mm³):	-0.20 ± 0.25 µg/mm³	2.5 ± 0.7 µg/mm³	
Maximum stress intensity factor (≥ 2.5 MPa $m^{1/2}$)	3.5 ± 0.3 MPa $m^{1/2}$		
Total fracture work (≥ 125000 J/m²)	160250 ± 16120 J/m²		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

March 1, 2013

Vertex-Dental B.V.
C/O Mason Diamond, DDS
Vice President, Regulatory and Quality Affairs
Qserve America
154 Main Street, Suite #2
CHARLESTOWN NH 03603

Re: K123220
Trade/Device Name: Vertex ThermoSens Rigid
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: September 25, 2012
Received: February 21, 2013

Dear Dr. Diamond:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123220

Device Name: Vertex™ ThermoSens Rigid

Indications For Use:

Vertex™ ThermoSens is a thermoplastic material that is intended to be used in the fabrication of removable full and partial dental prostheses. The product is based on a compounded mixture of Polyamide and pigments.

Prescription Use ____X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Mary S. Runner -S
Susan Runner DDS BA 2013.02.28 10:30:16 -05'00'

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123220